



NORTH CAROLINA DEPARTMENT OF ENVIRONMENTAL QUALITY  
DIVISION OF WASTE MANAGEMENT  
HAZARDOUS WASTE SECTION

## Management Standards for Hazardous Waste Pharmaceuticals Applicability and Waste Counting Guidance for Healthcare Facilities

On February 22, 2019, the Environmental Protection Agency (EPA) promulgated the Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine Rule (84 Federal Register (FR) 5816; February 22, 2019). This rule was effective on the federal level on August 21, 2019.

Two parts of this federal rule were effective in North Carolina on August 21, 2019:

- 1) The sewer prohibition (described at 40 CFR 266.505) which prohibits healthcare facilities and reverse distributors from sewer disposing hazardous waste pharmaceuticals. EPA administers and enforces this provision until North Carolina adopts it.
- 2) The amendment to the P075 nicotine listing (40 CFR 261.33) which removed FDA regulated nicotine replacements therapies (specifically nicotine gums, patches and lozenges) from being a P075 hazardous waste. This part of the rule applies to any site and is not specific only to healthcare facilities and reverse distributors.

With the exception of the sewer prohibition (which was effective in North Carolina on August 21, 2019), the provisions of 40 CFR 266 subpart P ("subpart P") must be adopted in North Carolina before they are effective. The anticipated effective date of the subpart P provisions is July 1, 2020.

This document provides an overview of the applicability of 40 CFR 266 subpart P to healthcare facilities once the requirements are effective in North Carolina (anticipated July 1, 2020).

**Step 1 - Site Applicability:** This rule applies to "healthcare facilities" and/or "reverse distributors."

Is your facility (or part of your facility) a "healthcare facility?" If your facility (or part of your facility) meets the below definition of a healthcare facility, then go to Step 2.

A **healthcare facility** means any person that is lawfully authorized to:

- 1) Provide preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or
- 2) Distributes, sell, or dispense pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals.

The definition of healthcare facility includes (but is not limited to):

- |   |                                 |
|---|---------------------------------|
| - wholesale distributors,   | - chiropractors,                |
| - third-party logistics providers that serve as forward distributors, | - long-term care facilities,    |
| - military medical logistics facilities,                              | - ambulance services,           |
| - hospitals,  | - pharmacies,                   |
| - psychiatric hospitals,  | - long term care pharmacies,    |
| - ambulatory surgical centers,  | - mail-order pharmacies,        |
| - health clinics, physicians' offices,                                | - retailers of pharmaceuticals, |
| - optical providers,  | - veterinary clinics, and       |
| - dental providers,   | - veterinary hospitals.         |

Is your facility a "reverse distributor"? If your facility meets the below definition of a reverse distributor and manages the applicable hazardous waste pharmaceuticals in Step 2, the requirements of 40 CFR 266 subpart P apply to your facility regardless of the generation category of the facility. You do not need to proceed to Step 3.

A **reverse distributor** means any person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purposes of facilitating or verifying manufacturer credit.

Any person, including forward distributors, third-party logistics providers, and pharmaceutical manufacturers, that processes prescription pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor.

If your facility (or part of your facility) is **not** a healthcare facility or reverse distributor, the requirements of 40 CFR 266 subpart P do not apply to your facility.

If you are not sure whether the provisions of this rule apply to your facility, contact your [Hazardous Waste Section Inspector](#). The following website link provides a map showing the regions and contact information of the Hazardous Waste Section Inspectors of the at the following website link:

[https://files.nc.gov/ncdeq/Waste+Management/DWM/HW/Compliance/Compliance\\_Map\\_by\\_Inspector.pdf](https://files.nc.gov/ncdeq/Waste+Management/DWM/HW/Compliance/Compliance_Map_by_Inspector.pdf)

**Step 2 - Waste Applicability:** This rule applies to "hazardous waste pharmaceuticals" generated at healthcare facilities and handled at reverse distributors. Definitions for pharmaceuticals, hazardous waste pharmaceuticals and non-hazardous waste pharmaceuticals are as follows.

**Pharmaceutical means** any drug or dietary supplement for use by humans or other animals; any electronic nicotine delivery system (e.g., electronic cigarette or vaping pen); or any liquid nicotine (e-liquid) packaged for retail sale for use in electronic nicotine delivery systems (e.g., pre-filled cartridges or vials).

The definition of pharmaceutical includes (but is not limited to):

- dietary supplements, as defined by the Federal Food, Drug and Cosmetic Act;
- prescription drugs, as defined by 21 CFR 203.3(y);
- over-the-counter drugs;
- homeopathic drugs;
- compounded drugs;
- investigational new drugs;
- pharmaceuticals remaining in non-empty containers;
- personal protective equipment contaminated with pharmaceuticals; and
- clean-up material from spills of pharmaceuticals.

This definition does not include:

- dental amalgam or
- sharps.

**Hazardous waste pharmaceutical** means a pharmaceutical that is a solid waste, as defined in 40 CFR 261.2, and exhibits one or more characteristics identified in part 261 subpart C or is listed in part 261 subpart D.

**Non-hazardous waste pharmaceutical** means a pharmaceutical that is a solid waste, as defined in 40 CFR 261.2, and is not listed in 40 CFR part 261 subpart D, and does not exhibit a characteristic identified in 40 CFR part 261 subpart C.

- The following are not hazardous waste pharmaceuticals and not subject to 40 CFR parts 260 through 273 (including not being subject to subpart P):
  - A pharmaceutical is not a solid waste, as defined in 40 CFR 261.2, and therefore not a hazardous waste pharmaceutical, if it is legitimately used/reused (e.g., lawfully donated for its intended purpose) or reclaimed.
  - An over-the-counter pharmaceutical, dietary supplement, or homeopathic drug is not a solid waste, as defined in 40 CFR 261.2, and therefore not a hazardous waste pharmaceutical, if it has a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for its intended purpose) or reclaimed. EPA has also indicated that other unsold retail items from healthcare facilities with reasonable expectation of legitimate use/reuse that are sent to reverse logistics center are not a solid waste.
- The following are not subject to 40 CFR parts 260 through 273, except as specified:
  - Household waste pharmaceutical means a pharmaceutical that is a solid waste, as defined in 40 CFR 261.2, but is excluded from being a hazardous waste under 40 CFR 261.4(b)(1) [the household hazardous waste exclusion]. Household waste pharmaceuticals, including those that have been collected by an authorized collector (as defined by the Drug Enforcement Administration), provided the authorized collector complies with the conditional exemption in 40 CFR 266.506(a)(2) and 266.506(b).
  - Pharmaceuticals being managed in accordance with a recall strategy that has been approved by the Food and Drug Administration in accordance with 21 CFR part 7 subpart C. Subpart P does apply to the management of the recalled hazardous waste pharmaceuticals after the Food and Drug Administration approves the destruction of the recalled items.
  - Pharmaceuticals being managed in accordance with a recall corrective action plan that has been accepted by the Consumer Product Safety Commission in accordance with 16 CFR part 1115. Subpart P does apply to the management of the recalled hazardous waste pharmaceuticals after the Consumer Product Safety Commission approves the destruction of the recalled items.
  - Pharmaceuticals stored according to a preservation order, or during an investigation or judicial proceeding until after the preservation order, investigation, or judicial proceeding has concluded and/or a decision is made to discard the pharmaceuticals.
  - Investigational new drugs for which an investigational new drug application is in effect in accordance with the Food and Drug Administration's regulations in 21 CFR part 312. Subpart P does apply to the management of the investigational new drug after the decision is made to discard the investigational new drug or the Food and Drug Administration approves the destruction of the investigational new drug, if the investigational new drug is a hazardous waste.

Hazardous waste pharmaceuticals generated or managed by entities other than healthcare facilities and reverse distributors (e.g., pharmaceutical manufacturers and reverse logistics centers) are not subject to subpart P. Other generators (other than healthcare facilities and reverse distributors) are subject to 40 CFR 262 for the generation and accumulation of hazardous wastes, including hazardous waste pharmaceuticals.

### **Step 3A – Category Applicability for Healthcare Facilities:**

**TOTAL Hazardous Waste for Site** = Hazardous Waste Pharmaceuticals + Non-Pharmaceutical Hazardous Waste

Is the TOTAL hazardous waste amount for the healthcare facility:

- Greater than 220 lbs. (100 kg) in a calendar month for non-acute hazardous waste; and/or
- Greater than 2.2 lbs. (1 kg) of acute hazardous waste in a calendar month; and/or
- Greater than 100 kg (220 pounds) of residues from a clean-up of acute hazardous waste generated in a calendar month?

Does the facility have a total hazardous waste amount for the healthcare facility that is:

- Greater than 2,200 lbs. (1000 kg) non-acute hazardous waste at any time; and/or
- Greater than 2.2 lbs. (1 kg) acute hazardous waste at any time; and/or
- Greater than 220 lbs. (100 kg) acute hazardous waste from a spill clean-up at any time?

If **YES** to either or both of the above questions, then healthcare facility must comply with 40 CFR 266 subpart P requirements (go to STEP 3B).

If **NO** to both questions, then healthcare facility must comply with sewer prohibition but has option to comply with very small quantity generator requirements (VSQG) in 40 CFR 262.14 or provisions of 40 CFR 266 subpart P.

The subpart P requirements are applicable to all reverse distributors regardless of their generator category.

**Step 3B - Counting Hazardous Waste for Healthcare Facilities:** Healthcare facilities that are large quantity generator (LQG) or small quantity generators (SQG) after calculating the **TOTAL** hazardous waste for the site (in Step 3A) must comply with subpart P requirements. Once applicability of subpart P is determined (based on TOTAL amounts of hazardous waste), the amount of hazardous waste pharmaceuticals does not need to be counted towards the generator category when managed under subpart P (40 CFR 262.13(c)(9)).

- When operating under subpart P, the healthcare facility may subtract the amount of hazardous waste pharmaceuticals from the total amount of HW to determine generator category.
- Healthcare facilities previously operating as an SQG or an LQG prior to operating under subpart P, will likely be able to reduce their hazardous waste generation category because hazardous waste generation is based only on non-pharmaceutical hazardous waste under subpart P.
- When a healthcare facility is able to downgrade their category because they do not have to count the hazardous waste pharmaceuticals managed under subpart P towards their generator category, they are still operating under subpart P and must meet subpart P requirements.
  - For example, when a SQG healthcare facility is able to downgrade to a VSQG healthcare facility because they no longer need to count the hazardous waste pharmaceuticals managed under subpart P, they are still required to meet subpart P requirements.
  - It is only the VSQG with the total hazardous waste (Hazardous Waste Pharmaceuticals + Non-Pharmaceutical Hazardous Waste) that has the option on whether to operate under the VSQG requirements of 40 CFR 262.14 or the subpart P requirements.